510(k): K101961

DEC 2 2 2010

II: 510(k) Summary

TrueVision® 3D Visualization and Guidance System

Submitter: TrueVision Systems Inc.
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Official Correspondent:
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Date: June 30, 2010

Device Trade Name	Classification Name	Common Name
TrueVision® 3D Visualization and Guidance System	Microscope, Surgical Class I per 21 CFR 878.4700 Camera, Ophthalmic Class II, per 21 CFR 886.1120 Picture archiving and communications System Class II, Per 21 CFR 892.2050	Visualization and Guidance System

Product Codes: HKI, NFJ

Substantial Equivalence:

The TrueVision® 3D Visualization and Guidance System is substantially equivalent to the following devices:

1) TrueVision® Visualization System for Microsurgery, Class 1 Device
TrueVision Systems, Inc.
Surgical Microscope/21CFR878.4700, EPT

2) Optronics EPIC Color Television Camera System
Karl Storz Imaging
Ophthalmic camera/21CFR 886.1850
K963333, HKI

3) OphthaVision Imaging System
MRP Group, Inc.
Ophthalmic camera/21CFR 886.1850
K980295, HKI

4) IMAGEnet Professional PC Software, Digital Image Management Software
Topcon Corporation
Picture archiving and communications system/21 CFR 892.2050
K082364, NFJ

Description of the Device Subject to Premarket Notification:

The TrueVision® 3D Visualization and Guidance System is a stereoscopic high-definition digital video camera and workstation, which operates as an adjunct to the surgical microscope during cataract surgery and the slit lamp microscope during pre-operative and post-operative image capture. The visualization system displays real-time images during eye surgery on a flat-panel, high-definition digital 3D display device positioned for live video image viewing by the surgeon and surgical personnel in the operating room.

The Cataract and Refractive Toolset system combines the TrueVision FDA-registered Class 1 Device (TrueVision® 3D Visualization System for Microsurgery) with proprietary TrueWare™ software (controlled via remote keyboard with included touchpad mouse) to provide enhanced visualization and surgical guidance assistance to the surgeon during specific procedures such as Limbal Relaxing Incision, Capsulorhexis, and toric IOL positioning.

Using standard pre-operative clinical data, together with surgeon-driven, onscreen templates and guides, the Refractive Cataract Toolset provides graphical assistance to the surgeon as desired during the surgery. Guidance

applications include incision templates to optimize the position of limbal relaxing incisions, sizing and positioning of capsulorhexis tears, and rotational alignment of toric intraocular lenses (toric IOL).

Indications for Use:

The TrueVision® 3D Visualization and Guidance System is an adjunct imaging tool that provides onscreen guidance with alignment, orientation, and sizing for eye surgery. The system is intended for use as a preoperative and postoperative image capture tool with visualization and guidance provided during anterior segment ophthalmic surgical procedures, including limbal relaxing incisions, capsulorhexis and toric intraocular lens (toric IOL) positioning. The system utilizes surgeon confirmation at each step for planning and positioning of guidance templates.

Performance Standards:

None. There are no mandatory performance standards for this type of device.

Basis for Determination of Substantial Equivalence:

The TrueVision® 3D Visualization and Guidance System described in this submission is substantially equivalent to the predicate device(s) listed above. All of the devices are used in ophthalmic imaging applications, provide means for capture, storage, and manipulation of said images, and provide practitioners with tools to provide visualization or surgical guidance assistance. All of the devices contain similar system components (camera, processor, and display), and all are used on the same anatomical location. The minor differences between the TrueVision 3D Visualization and Guidance System and the listed predicate devices do **not** raise any new questions of safety or of effectiveness in comparison to the predicate devices.

Performance Data:

Performance verification and validation testing was completed to demonstrate that the device performance complies with specifications and requirements identified for the TrueVision® 3D Visualization and Guidance System. This was accomplished by software verification testing and a nonsignificant risk clinical study. All criteria for this testing were met and results demonstrate that the TrueVision® 3D Visualization and Guidance System meets all performance specifications and requirements.

Conclusions:

As described in this 510(k) Summary, all testing deemed necessary was conducted on the TrueVision® 3D Visualization and Guidance System to ensure that the device is safe and effective for its intended use and is substantially

equivalent to legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

TrueVision Systems, Inc.
c/o Dr. A. Burton Tripathi
Vice President, Product Development
114 East Haley Street, Suite L
Santa Barbara, CA 93101

DEC 2 2 2010

Re: K101861
Trade/Device Name: TrueVision 3D Visualization and Guidance System
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: II
Product Code: HKI, NFJ, EPT
Dated: Not Dated
Received: October 14, 2010

Dear Dr. Tripathi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Original Premarket Notification K101861

Device Name: TrueVision® 3D Visualization and Guidance System

Indications for Use:

DEC 2 2 2010

The TrueVision® 3D Visualization and Guidance System is an adjunct imaging tool that provides onscreen guidance with alignment, orientation, and sizing for eye surgery. The system is intended for use as a preoperative and postoperative image capture tool with visualization and guidance provided during anterior segment ophthalmic surgical procedures, including limbal relaxing incisions, capsulorhexis and toric intraocular lens (toric IOL) positioning. The system utilizes surgeon confirmation at each step for planning and positioning of guidance templates.

Prescription Use __X___

(Part 21 CFR 801 Subpart D)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K101861